

REMARKS

Upon entry of this reply, claims 27 and 29 are canceled, resulting in claims 1-12, 15-27, and 29 now being canceled; claims 13 and 37 are amended; leaving claims 13, 14, 28, and 30-37 will be pending. Claim 13 is independent.

Summary of March 6, 2007 Interview

Applicants express appreciation for the courtesy extended by Examiner Ewoldt to Applicants' representative, Sean Myers-Payne, during a March 6, 2007 telephone interview.

During the interview, Applicants' representative emphasized that the subject matter of some dependent claims was not taught or suggested by the prior art. The Examiner suggested that Applicants amend the independent claims to recite such subject matter, and agreed to consider such amendments and accompanying remarks presented in writing.

The present Amendment incorporates amendments and remarks discussed with the Examiner during the interview.

Claim Rejections – 35 U.S.C. § 103

The Office Action maintains the rejection of claims 13, 14, and 27-36 under 35 U.S.C. § 103(a) as allegedly obvious over Nestle et al. (Nature Medicine 4(3):328-332 (1998)) in view of Gu et al. (Acta Med. Nakasaki 42: 19-24 (1997)).

In response, Applicants note that Nestle et al. describe the use of a peptide "cocktail" or "lysate" (both of which would include a number of peptides). The authors

specifically state that “[m]ultiple peptides were used to diminish the chances of immune escape in a given patient.” (Page 328, right column, lines 16-17.) Thus, Nestle et al. specifically teaches away from the use of a single peptide or antigen. The Gu et al. publication, on the other hand, appears to be directed to the use of a single discrete peptide sequence as an antigen.

Applicants respectfully submit that a person of ordinary skill in the art cannot be expected to have combined the teachings of Nestle et al. with those of the Gu et al. publication. Nestle et al. teaches that *multiple* peptides are needed in order to achieve a satisfactory result. The Gu et al. publication, on the other hand, only uses one peptide sequence as an antigen. Applicants respectfully submit that a person skilled in the art would not be motivated to replace the *multiple* peptides required by Nestle et al. with the *single* peptide of Gu et al. And given the strong statement by Nestle et al. of the need for multiple peptides, there would not be a reasonable expectation of success.

Applicants reiterate the positions raised in prior responses, particularly those related to unexpectedly good results of the present invention as related to the cited art. Those arguments are as applicable today as they were when they were previously made. For the sake of brevity, and because the Examiner has made clear his position with regard to those arguments, those arguments are not restated here.

For at least the foregoing reasons, Applicants respectfully request that the rejection for obviousness be withdrawn.

The Office Action also maintains the rejection of claims 13, 14, and 27-36 under 35 U.S.C. § 103(a) as allegedly obvious over Nestle et al. in view of Gu et al. (Cancer Research 58: 3385-3390 (1998)).

In response, Applicants note that Nestle et al. describe the use of a peptide “cocktail” or “lysate” (both of which would include a number of peptides). The authors specifically state that “[m]ultiple peptides were used to diminish the chances of immune escape in a given patient.” (Page 328, right column, lines 16-17.) Thus, Nestle et al. specifically teaches away from the use of a single peptide or antigen. The Gu et al. publication, on the other hand, appears to be directed to the use of a single discrete peptide sequence as an antigen.

Applicants respectfully submit that a person of ordinary skill in the art cannot be expected to have combined the teachings of Nestle et al. with those of the Gu et al. publication. Nestle et al. teaches that *multiple* peptides are needed in order to achieve a satisfactory result. The Gu et al. publication, on the other hand, only uses one peptide sequence as an antigen. Applicants respectfully submit that a person skilled in the art would not be motivated to replace the *multiple* peptides required by Nestle et al. with the *single* peptide of Gu et al. And given the strong statement by Nestle et al. of the need for multiple peptides, there would not be a reasonable expectation of success.

Applicants reiterate the positions raised in prior responses, particularly those related to unexpectedly good results of the present invention as related to the cited art. Those arguments are as applicable today as they were when they were previously made. For the sake of brevity, and because the Examiner has made clear his position with regard to those arguments, those arguments are not restated here.

For at least the foregoing reasons, Applicants respectfully request that the rejection for obviousness be withdrawn.

The Office Action rejects claims 13, 14, and 27-36 under 35 U.S.C. § 103(a) as allegedly unpatentable over Kohno et al. (Cellular Immunology 168: 211-219 (1996)) in view of Gu et al. (1997), Nagarkatti et al. (J. Immunol. 144(12): 4898-4905 (1990)), and Terao et al. (Biotherapy 8: 143-151 (1995)).

In response, Applicants respectfully note that the claims require, at least, “a hydrophobized polysaccharide and an antigen.” Applicants again submit, as previously submitted, that Kohno et al. does not disclose a hydrophobized polysaccharide and an antigen.

Kohno et al. disclose sugi basic protein (SBP) conjugated to pullulan (P). While the Office Action fails to state, presumably, the Action is asserting that SBP is the “antigen” and P is the “polysaccharide.” However, it is unclear how the Office Action concludes that the polysaccharide is “hydrophobized” when Kohno et al. does not disclose that it is so-modified.

According to Kohno et al., the SBP-P conjugate is made by activating the P with cyanuric chloride, then combining the activated P with SBP. There is nothing in Kohno et al. that suggests that the cyanuric chloride acts as a “coupling agent,” which might “bridge” the P to the SBP. Thus, there is nothing in Kohno et al. to suggest that any portion of cyanuric chloride remains attached to either the P or the SBP. In the absence of such specific suggestion, it must be concluded that the polysaccharide of Kohno et al. is *not* hydrophobized.

The Action asserts that Kohno et al. differs from the claimed invention only in that it does not teach a method of inducing cellular immunity *in vivo* or the use of the ErbB-2 antigen. As noted above, Kohno et al., also does not disclose a hydrophobized polysaccharide.

The Action cites Gu et al. for teaching that ErbB-2 is overexpressed in a wide range of adenocarcinomas. Nagarkatti et al. is cited for teaching that Th1 CD4+ T cells can mediate tumor rejection. Terao et al. is cited by the Office for teaching that Th1 CD4+ T cells expressing IFN- γ can be used in anti-tumor immunotherapy, particularly against poorly immunogenic tumors.

As noted, the primary publication relied upon by the Office Action fails to teach or suggest the use of a hydrophobized polysaccharide. The Action also fails to explain why Kohno et al. would have been modified to include a hydrophobized polysaccharide. There is nothing in Kohno et al. that would lead to the addition of, or the use of, a hydrophobized polysaccharide. In the absence of such motivation to modify the primary teaching, the rejection is untenable and should be withdrawn.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejects claims 27 and 37 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. In response, without acquiescing to or agreeing with the rejection, Applicants note that claim 27 has been canceled and claim 37 has been amended.

In view of these amendments and remarks, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

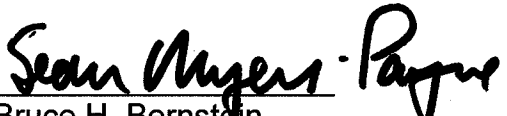
CONCLUSION

In view of the foregoing amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
Hiroshi SHIKU et al.


Bruce H. Bernstein
Reg. No. 29,027 42,920

April 30, 2007
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191